Valid from: 15-12-2023
Replaces: 18-08-2023

# Batch Release Certificate

**Product name:** **Dextran 70 JP**

**Specification No.:** **40125**

**Batch No.:** xxxxxx
**Manufacturing date:** mmmm_yyyy
**Retest date (3 years):** mmmm_yyyy

**Manufacturing sites:** Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark
**DKMA No.:** 254629
**GMP certificate No.:** DK API-H 10000578, DK API-V 10000639
**FDA establishment No.:** FEI 3002807874
**FDA facility classification:** Acceptable
**EDQM certificate No.:** Certificates for Dextran 1, 40, 60 & 70 Ph.Eur. available

| Method: | Parameter: | Results of analysis: | | Limits: |
|---|---|---|---|---|
| JP | Appearance of solution: | Complies | | Clear and colorless |
| JP | Identification: | Complies | * | Complies |
| JP | Assay (dextran after drying, % w/w): | x.x | | 98.0 – 102.0 |
| DF034 | Average molecular mass, Mw: | x,xxx | | app. 70,000 |
| JP | Viscosity, intrinsic, dL/g: | x.xx | ** | 0.21 – 0.26 |
| JP | Viscosity, intrinsic, high fraction, dL/g: | x.xx | ** | ≤0.35 |
| JP | Viscosity, intrinsic low fraction, dL/g: | x.xx | ** | ≥0.10 |
| JP | pH (6% solution): | x.x | | 5.0 – 7.0 |
| JP | Nitrogen containing substances, ppm N: | x | | ≤100 |
| JP | Chloride, % w/w: | Complies | | ≤0.018 |
| JP | Reducing substances per g: | Complies | | ≤10 (mg glucose) |
| JP | Loss on drying (105°C, 6h), % w/w: | x.x | | ≤5.0 |
| JP | Residue on ignition, % w/w: | x.x | | ≤0.1 |
| JP | Pyrogenes (groups of 3 rabbits): | Not tested | | Complies |
| JP | Antigenicity: | Not tested | | Complies |

References to official monographs are to be considered as current editions.

EDQM refers to 'European Directorate for the Quality of Medicines and Healthcare'. DKMA refers to 'Danish Medicines Agency'

*) Test is not carried out. The identification of the product is assured througt strict adherence to established GMP rules throughout the manufacturing pro

**) Test is performed acoording to modifed method that is correlated to Mw.

We confirm that no class 1, class 2 and class 3 solvent, cf. ICH Q3C and VICH GL 18, is used in the manufacturing of this product.

We confirm that no metal catalysts or metal reagents are used in the manufacturing of this product. Elemental impurities, cf. ICH Q3D are unlikely to be present.

**CERTIFICATE OF CONFORMITY**

**I hereby certify that the above information is authentic and accurate. This batch of Active Pharmaceutical Ingredient has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements for active starting materials and with the above mentioned specifications. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.**

Date (dd.mm.yyyy):

Qualified Person, Heidi Skjødt Andersen, M.Sc. Pharm

PHARMACOSMOS A/S
ROERVANGSVEJ 30
DK-4300 HOLBAEK
DENMARK

TELEPHONE: +45 59 48 59 59
E-MAIL: info@pharmacosmos.com
WEB-SITE: www.pharmacosmos.com

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